

## THE UNITED STATES PATENT AND TRADEMARK OFFICE

Thomas R. COOLIDGE et al.

Group Art Unit: 1653

Appln. No.: 09/851,738

Examiner: Samuel W. LIU

Filed: May 9, 2001

Atty. Docket: 18528.613 / 0213-DIV-9

For: Metabolic Intervention with GLP-1

Confirmation No. 4849

to Improve the Function of Ischemic

and Reperfused Tissue

## **INFORMATION DISCLOSURE STATEMENT**

Mail Stop RCE

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

The attention of the Examiner is invited to the documents listed on the attached Form PTO-1449. Copies of the listed documents are submitted herewith.

It is respectfully requested that the information above be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom. However, Applicants make no representation or admission that the cited references constitute "prior art" to the claims of the present application.

Further, Applicants wish to bring to the attention of the Examiner, the following copending applications:

1. U.S. Application No. 10/091,258

Filed: March 5, 2002

Entitled: Compositions and Methods for Treating Peripheral Vascular

Disease; and

2. U.S. Application No. 10/913,309

Filed: August 6, 2004

Entitled: Metabolic Intervention with GLP-1 or its Biologically Active

Analogue to Improve the Function of the Ischemic and

Reperfused Brain

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## **CERTIFICATION AND/OR FEE**

Because this Information Disclosure Statement is being submitted after issuance of the first action on the merits of the above-captioned application, a fee of \$180.00 is due pursuant to 37 C.F.R. § 1.17(p). Applicants request that this fee be charged to Deposit Account No. 50-2387 referencing docket number 18528.613.

Respectfully submitted,

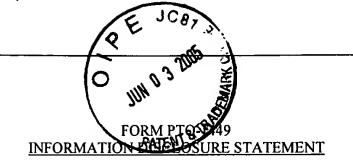
David R. Marsh (Reg. No. 41,408)

Rachel L. adams

Rachel L. Adams (Reg. No. 54,660)

Date: <u>June 3, 2005</u>

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**EXAMINER** 

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DATE CONSIDERED

AA1	DOCUMENT NUMBER	DATE	U.S. PATENT DOCUMENTS		SUB-	<del></del>
AA1		DATE			SUB-	
AA1	NUMBER		I NIANE	OT A CC	CLASS	EII DIC DATE
$\alpha \alpha i$	4,976,959	12/1990	NAME Berger, Jr., et al.	CLASS	CLASS	FILING DATE
	2002/0061838 A1	5/2002				
AB1	2002/0001838 A1	3/2002	Holmquist et al.			
AC1					+	
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			FOREIGN PATENT DOCUMENTS		1	
	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
AF1	98/43658	10/1998	PCT			Ye: No
			n om			Yes
AG1	00/16797	3/2000	PCT			No
AH1						Ye No
AI1						Ye
7117						No Ye
AJ1						No
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)						
AK l					ı Men vs. W	omen - The
AL1	Bhat et al., "Skeletal Muscle Mitochondrial DNA Injury in Patients With Unilateral Peripheral Arterial Disease", Circulation, Vol. 99, pp. 807-812 (1999)					
AM1	Boska et al., " <sup>31</sup> P MRS Studies of Exercising Human Muscle at High Temporal Resolution", Magnetic Resonance in Medicine, Vol. 41, pp. 1145-1151 (1999)					
ANI	Brand et al., "Diabetes, Intermittent Claudication, and Risk of Cardiovascular Events - The Framingham Study", Diabetes, Vol. 38, pp. 504-509 (1989)					
AO1	Bullock et al., "Tissue Distribution of Messenger Ribonucleic Acid Encoding the Rat Glucagon-Like Peptide-1 Receptor", Endocrinology, Vol. 137, No. 7, pp. 2968-2978 (1996)					
	Clanton et al., "Physiological and Genomic Consequences of Intermittent Hypoxia Invited Review: Adaptive Responses of Skeletal Muscle to Intermittent Hypoxia: the Known and the Unknown", J. Appl. Physiol., Vol. 90, pp. 2476-2487 (2001)					
A	AKI ALI ANI	Abbott et al., "Tramingham State I Bhat et al., "Ske Circulation, Vo  Boska et al., "31 in Medicine, Vo  Brand et al., "Diabetes, Vol. 3  Bullock et al., "Receptor", Ende	Abbott et al., "The Impact of Framingham Study", JAMA  Bhat et al., "Skeletal Muscle Circulation, Vol. 99, pp. 807  Boska et al., "31P MRS Studin Medicine, Vol. 41, pp. 11  Brand et al., "Diabetes, Interdiabetes, Vol. 38, pp. 504-5  Bullock et al., "Tissue Distr Receptor", Endocrinology, Vol. 11	Abbott et al., "The Impact of Diabetes on Survival Following Normalism Study", JAMA, Vol. 260 No. 23, pp. 3456-3460 ( Bhat et al., "Skeletal Muscle Mitochondrial DNA Injury in Pation Circulation, Vol. 99, pp. 807-812 (1999)  Boska et al., "31P MRS Studies of Exercising Human Muscle at in Medicine, Vol. 41, pp. 1145-1151 (1999)  Brand et al., "Diabetes, Intermittent Claudication, and Risk of Obiabetes, Vol. 38, pp. 504-509 (1989)  Bullock et al., "Tissue Distribution of Messenger Ribonucleic And Receptor", Endocrinology, Vol. 137, No. 7, pp. 2968-2978 (1989)	Abbott et al., "The Impact of Diabetes on Survival Following Myocardial Infarction in Framingham Study", JAMA, Vol. 260 No. 23, pp. 3456-3460 (1988)  Bhat et al., "Skeletal Muscle Mitochondrial DNA Injury in Patients With Unilateral Peciculation, Vol. 99, pp. 807-812 (1999)  Boska et al., "31P MRS Studies of Exercising Human Muscle at High Temporal Resolution Medicine, Vol. 41, pp. 1145-1151 (1999)  Brand et al., "Diabetes, Intermittent Claudication, and Risk of Cardiovascular Events Diabetes, Vol. 38, pp. 504-509 (1989)  Bullock et al., "Tissue Distribution of Messenger Ribonucleic Acid Encoding the Rate Receptor", Endocrinology, Vol. 137, No. 7, pp. 2968-2978 (1996)	Abbott et al., "The Impact of Diabetes on Survival Following Myocardial Infarction in Men vs. W. Framingham Study", JAMA, Vol. 260 No. 23, pp. 3456-3460 (1988)  Bhat et al., "Skeletal Muscle Mitochondrial DNA Injury in Patients With Unilateral Peripheral And Circulation, Vol. 99, pp. 807-812 (1999)  Boska et al., "31P MRS Studies of Exercising Human Muscle at High Temporal Resolution", Magin Medicine, Vol. 41, pp. 1145-1151 (1999)  Brand et al., "Diabetes, Intermittent Claudication, and Risk of Cardiovascular Events - The Frami Diabetes, Vol. 38, pp. 504-509 (1989)  Bullock et al., "Tissue Distribution of Messenger Ribonucleic Acid Encoding the Rat Glucagon-L Receptor", Endocrinology, Vol. 137, No. 7, pp. 2968-2978 (1996)

**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

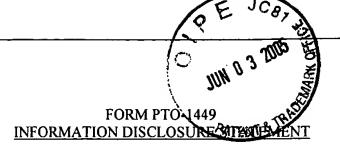
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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AA2	Dawson et al., "A Comparison of Cilostazol and Pentoxifylline for Treating Intermittent Claudication", The American Journal of Medicine, Vol. 109, pp. 523-530	
	AB2	DuPont et al., "Marijuana and Benzodiazepines in Patients Receiving Methadone Treatment", JAMA, Vol. 261, No. 23, pp. 3409 (1989)	
	AC2	Gray et al., "Risk Factor Clustering in the Insulin Resistance Syndrome - The Strong Heart Study", American Journal of Epidemiology, Vol. 147, No. 9, pp. 869-878 (1998)	
	AD2	Green, "Regarding 'Phosphorus 31 Nuclear Magnetic Resonance Spectroscopy Suggests a Mitochondrial Defect in Claudicating Skeletal Muscle'", <u>Journal of Vascular Surgery Online</u> , Vol. 33, No. 5, pp. 1-2 (2001)	
	AE2	Hamilton et al., "Insulin Reduction of Cerebral Infarction Due to Transient Focal Ischemia", J. Neurosurg., Vol. 82, pp. 262-268 (1995)	
	AF2	Hiatt et al., "Carnitine Metabolism During Exercise in Patients with Peripheral Vascular Disease", J. Appl. Physiol., Vol. 62, No. 6, pp. 2383-2387 (1987)	
3.	AG2	Iribarren et al., "Glycemic Control and Heart Failure Among Adult Patients with Diabetes", Circulation, Vol. 103, pp. 2668-2673 (2001)	
·	АН2	Irwin et al., "The Xenopus proglucagon gene encodes novel GLP-1-like peptides with insulinotropic properties", Proc. Natl. Acad. Sci. USA, Vol. 94, pp. 7915-7920 (1997)	
-	AI2	Matz, "Does Control of Diabetes Prevent Vascular Complications?", <u>JAMA</u> , Vol. 261, No. 23, pp. 3409-3410 (1989)	
	AJ2	Reilly et al., "Cilostazol: Treatment of Intermittent Claudication", The Annals of Pharmacotherapy, Vol. 35, pp. 48-56 (2001)	
	AK2	Scott et al., "Glucose and Insulin Therapy in Acute Stroke; Why Delay Further?", Q J Med, Vol. 91, pp. 511-515 (1998)	
	AL2	Serre et al., "Exendin-(9-39) is an Inverse Agonist in the Murine Glucagon-Like Peptide-1 Receptor: Implications for Basal Intracellular Cyclic Adenosine 3',5'-Monophosphate Levels and β-Cell Glucose Competence", Endocrinology, Vol. 139, No. 11, pp. 4448-4454 (1998)	
EXAMINER	L	DATE CONSIDERED	

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May 9, 2001 OTHER (Including Author, Title, Date, Pertinent Pages, etc.) Sissman et al., "Patent Ductus Arteriosus, Prematurity, and Respiratory Distress Syndrome", JAMA, Vol. 261, No. AA3 23, pp. 3410 (1989) Weitz et al., "Diagnosis and Treatment of Chronic Arterial Insufficiency of the Lower Extremities: A Critical AB3 Review", Circulation, Vol. 94, pp. 3026-3049 (1996) AC3 AD3 AE3 AF3 AG3 AH3 AI3 AJ3 AK3 AL3 DATE CONSIDERED **EXAMINER** 

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